REMARKS

Claims 39-42, 45, and 46 have been canceled, without prejudice. New claims 47-50 have been added to more particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Support for the new claims may be found in the specification, thus, no new matter has been introduced. For example, support for claims 47 and 48 can be found on page 6, lines 15-31 and on page 12, line 24 to page 13, line 15. Support for claims 49 and 50 can be found on page 37, line 25 to page 43, line 24. A copy of the claims as currently pending is attached as Appendix A.

The Rejections Under 35 U.S.C. § 112, Second Paragraph Are Obviated

Claims 40-42 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claims 40-42 have been canceled thus making the rejections immaterial.

In view of the foregoing, Applicants request that the Examiner withdraws the rejections under 35 U.S.C. §112, second paragraph.

The Rejections Under 35 U.S.C. § 112, First Paragraph Should Be Withdrawn

Claims 39-42, 45, and 46 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time of filing. The Examiner further rejects the claims under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as enable one skilled in the art to which it pertains to make and/or

use the invention. Applicants believe these rejections should be withdrawn for the reasons stated below.

The Examiner contends that the specification fails to describe a cellular protein that is an upstream activator of Src kinase and also interacts with a HBV protein. Consequently, one of skill in the art would not know which upstream activator of Src kinase to target for inhibition. Applicants have added new claims which do not require that the identity of the upstream activator of Src kinase be known. In order to practice the methods of the invention, the activity of Src kinase itself must be determined. One of skill in the art can easily use an *in vitro* assay to determine the level of Src kinase activity.

The Examiner also alleges that the specification fails to adequately describe the genus of compounds to be used in the methods of the invention. This is because no physical or chemical properties of the genus are disclosed. Applicants contend that the specification has provided a description of the unifying characteristic that distinguishes the members of this genus from others, *i.e.*, the ability to reduce the activation of Src kinase. The specification teaches a variety of assays for the identification of compounds that result in decreased Src kinase activity (*see e.g.*, Sections 5.5 and 5.5.1 of the instant specification on pages 37-43). Thus, by highlighting the pertinent characteristic that a compound must possess to inhibit HBV replication in the claimed methods, the Applicants have defined the characteristic of the claimed genus that distinguishes it from others and should be free from having to detail each and every compound that would fit into this category. In the present day, where high throughput screening is commonplace, one skilled in the art could easily use the teachings of the specification to distinguish useful compounds from those that are not.

Given the teaching of the instant specification, one of skill in the art would recognize that the only characteristic one needed to identify to determine whether a

compound falls within the claimed genus is the ability of a compound to reduce Src kinase activity when compared to Src kinase activity in the absence of the compound.

Undue experimentation is experimentation that would require a level of ingenuity *beyond* what is expected from one of ordinary skill in the field. *Fields v. Conover,* 170 U.S.P.Q. 276, 279 (C.C.P.A. 1971). The factors that can be considered in determining whether an amount of experimentation is undue have been listed in *In re Wands,* 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Among these factors are: the amount of effort involved, the guidance provided by the specification, the presence of working examples, the amount of pertinent literature and *the level of skill in the art.* The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, so long as it is merely routine. *Id.* Far from being an undue experimental burden, identification of compounds that reduce Src kinase activity with an *in vitro* assay is common place.

In view of the foregoing, Applicants request that the Examiner withdraws the rejections under 35 U.S.C. §112, first paragraph.

CONCLUSION

Applicant respectfully requests that the amendments and remarks made herein be entered and made of record in the file history of the present application. Withdrawal of the Examiner's rejections and a notice of allowance are earnestly requested. If any issues remain

in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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Date: November 9, 2001

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Enclosure

APPENDIX A
PENDING CLAIMS AS OF NOVEMBER 9, 2001
U.S. PATENT APPLICATION SERIAL NO. 09/096,589
ATTORNEY DOCKET NO. 5914-065-999

47. A method for inhibiting Hepatitis B virus (HBV) replication comprising administering a compound that inhibits enhanced activity of Src kinase wherein said enhanced activity results from the presence of HBx.

48. A method for inhibiting Hepatitis B virus (HBV) replication in a cell wherein Src kinase activity is enhanced comprising administering a compound that reduces the enhanced activation of Src kinase activity to levels comparable to those observed in the absence of HBV.

49. The method of Claim 47 or 48 wherein the compound that inhibits said enhanced activity of Src kinase is determined by an *in vitro* assay comprising:

a) contacting a cell expressing HBx with the compound;

b) determining whether levels of Src kinase activity are reduced in those cells contacted with the compound as compared to levels of Src kinase activity in cells expressing HBx in the absence of the compound.

50. The method of claim 47 or 48 wherein said compound inhibits a Src kinase signaling cascade component other than Src kinase as determined by an *in vitro* assay comprising:

a) contacting a Src kinase with said compound; and

b) determining whether levels of Src kinase activity in the presence of said compound are substantially equal to levels of Src kinase activity in the absence of said compound.